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REPORT OF THE WORKING GROUP

ON

STANDARDS, TESTING,

AND CERTIFICATION

The Report of the Working Group on Standards, Testing, and Certification is the result of the work of its authors and contributors. The Report does not represent the final position of the Government of Canada.

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Preface

About the Working Group

Under the auspices of the Federal Government Task Force on Europe 1992, the Working Group on Standards Testing and Certification is charged with assessing, for Canadian business interests, the implications of the European Community's (EC's) policy on technical standards. The object is to enhance awareness of this EC policy among those in Canada that need to know. Specifically, the Working Group is to:

- identify, monitor, and review EC measures on standards and technical harmonization for the EC's internal market;
- assess and evaluate those measures that may offer particular opportunities or that appear to be of concern to Canada;
- develop recommendations for action.

The Working Group includes representatives of federal agencies and departments with regulatory, economic, and trade-related responsibilities—including members of the Interdepartmental Committee on Standards Policy (ICSP)—and representatives of the Standards Council of Canada (SCC). The Interdepartmental Committee on Standards Policy (ISP) includes representatives from:

- External Affairs and International Trade Canada (*Chair*)
- Agriculture Canada
- Atomic Energy of Canada
- Canada Mortgage and Housing Corporation
- Communications Group
- Consumer and Corporate Affairs
- Energy, Mines and Resources
- Environment Canada
- Fisheries and Oceans
- Forestry Canada
- Health and Welfare Canada
- Industry, Science and Technology Canada
- Labour Canada
- National Defence
- National Research Council
- Supply and Services Canada
- Transport Canada
- The Standards Council of Canada (*Associate member*)

About the Report

The Report of the Working Group on Standards, Testing, and Certification is based on comments from the ICSP and reports about EC policy developments from the Canadian mission to the EC in Brussels and from other Canadian missions in Europe. Supplementary information has been obtained through consultation with representatives of Canadian industry, with officials from the EC Commission, and with representatives of European and international organizations.

The Chairman of both the ICSP and the Working Group is Paul S. H. Lau, Director, Industrial Trade Policy Division, External Affairs and International Trade Canada, who bears the entire responsibility for this report. The report's principal author is Keith Aird, formerly Deputy Director of Industrial Trade Policy, currently the Forest Products and Standards Attaché at the Canadian mission to the European Community.

The contributions of the members of the ICSP and of the members of the Committee on International Trade Standards Matters (Standards Council of Canada) are gratefully acknowledged.

Abbreviations Used in the Text

AECMA	Association Européenne des Constructeurs de Matériel Aérospatial
AFNOR	Association Française de Normalisation
BPIB	Bureau de promotion des industries du bois
BSI	British Standards Institution
CCA	CENELEC Certification Agreement (for electrical low-voltage goods)
CECC	CENELEC Electronic Components Committee
CEN	European Committee for Standardization
CENCER	Certification Association of CEN
CENELEC	European Committee for Electrotechnical Standardization
CEPT	European Conference of Posts and Telecommunications
CGSB	Canadian General Standards Board
CNC/IEC	Canadian National Committee of the International Electrical Commission
CNC/ISO	Canadian National Committee of the International Organization for Standardization
CSA	Canadian Standards Association
COFI	Council of Forest Industries of British Columbia

DIN	Deutsches Institut für Normung E.V.
EC	European Community
ECISS	European Committee for Iron and Steel Standardization
ECU	European currency unit
EEC	European Economic Community
EFTA	European Free Trade Association (comprises Austria, Finland, Iceland, Norway, Sweden, and Switzerland)
EN	Europaische Normen (European standard)
EOTC	European Organization for Testing and Certification
ETSI	European Telecommunications Standards Institute
HAR	CENELEC agreement on the use of a commonly agreed marking for cables and cords complying with harmonized specifications
ICSP	Interdepartmental Committee on Standards Policy
IEC	International Electrotechnical Commission
ISDN	Integrated Services Data Network
ISO	International Organization for Standardization
JTC1	Joint Technical Committee 1
KEMA	Keuring van Electrotechnische Materialen (Organization for the inspection of electrotechnical materials—Netherlands)
LVD	Low Voltage Directive
MOU	Memorandum of Understanding
NSS	National Standards System
OEM	Original equipment manufacturer
PTT	Postal, telegraph, and telephone administration
QA	Quality assurance
QMI	Quality Management Institute
SCC	Standards Council of Canada
TUV	Technischer Uberwachungs-Verein (Organization for technical supervision—Germany)

Executive Summary

Introduction

- As part of the Europe 1992 initiative, which includes free internal movement of goods, the EC is seeking to remove technical barriers to trade between member states. "Reference to standards" is also expected to open markets for government procurement in member states.
- The creation of the "internal market" is important to businesses in the Community.
- The EC cooperates with national, regional, and international standards organizations.
- Market access for, and acceptance and competitiveness of, Canadian exports to the EC are affected by technical regulations, voluntary standards, and conformity procedures that differ from one member state to another.
- The EC has recently adopted an ambitious, comprehensive, and complex policy for eliminating technical barriers, turning much control over to non-governmental bodies and (possibly) to the EC Commission.

EC Policy on Standards

- The objectives of the new EC policy are to remove existing technical barriers, to prevent new barriers being erected, and to encourage industrial development in the Community, particularly competitiveness and technological adaptation in the information technology, telecommunications, construction, and food products sectors.
- In the past, the EC has tried to minimize technical barriers by challenging certain national standards in the European Court of Justice.
- "Mutual recognition" of voluntary national standards is now being enforced through European Court challenges based on earlier findings, mainly the 1979 Cassis de Dijon case. A recent example is the October 1990 finding against minimum fat restrictions in Italian regulations for cheese.
- Technical regulations on a number of products, such as automobiles and electronics, were harmonized in 200 detailed EC Directives ("old approach").
- Harmonization of technical regulations is now being effected by legislating "essential requirements" related to health, safety, and environmental protection. The "essential requirements" are then incorporated into European standards by CEN, CENELEC, and ETSI, who have been given mandates and financial assistance by the EC Commission.
- Detailed technical standards are nevertheless still being legislated in certain sectors (i.e., motor vehicles, tractors, food products, pharmaceuticals, and chemicals).
- Information procedures have been put in place to help prevent the creation of new technical barriers in member states.

- The EC is also concerned to bring about, as soon as possible, the mutual recognition of testing and certification regimes in member states. The proposed framework for mutual recognition in this area includes creating standard procedures for assessing conformity with regulations, harmonized standards for QA and laboratory practices, an organization to coordinate conformity assessment and support for creating new institutions as needed, and the negotiation of mutual recognition agreements with third countries.

From Policy into Practice

- Much progress has been made in legislating some shared standards and proposals for harmonizing others, but implementation has not been as rapid.

- The EC Commission therefore prepared a Green Paper focussing on the problems and proposing solutions. Much of the emphasis is on private sector participation, procedural changes to expedite work, new organizations (where necessary), and obtaining international cooperation.

- EFTA countries have laid the groundwork for virtually complete participation in the new EC policy. Traditional EFTA membership in CEN and CENELEC has been supplemented by EC-EFTA cooperation agreements concerning the exchange of information about technical regulations and standards.

- In addition, if the EFTA countries adopt the EN 29000 and EN 45000 standards, they may also conclude agreements with the EC for mutual recognition of testing and certification. A major step in this direction was the April 1990 EC-EFTA agreement with CEN and CENELEC to establish the EOTC. These initiatives could further improve market access for EFTA countries, who already enjoy a duty-free access to the EC not available to Canadian exporters.

EC Policy and Canadian Trade Interests

- Certain product sectors (viz., food stuffs, information technology, telecommunications, and construction products), whose standardization the EC Commission has cited as important, are also important from the viewpoint of Canadian exporters.

- Traditional technical differences between the EC and Canada are not likely to disappear under the new policy. These differences evolved for reasons such as the local preferences of consumers and government procurement administrators for voluntary national standards on food composition, residential construction, and so on. Technical regulations also reflect varying approaches to public safety, health, and environmental issues.

- However, Canadian exporters can broaden their market to all EC members if they meet either the voluntary national standards of one member state or the newly emerging "European standards".

- The biggest drawback is the lack of coordination in testing and certification among EC member states. Canadian firms can use approaches such as simple declarations of conformity, registration of their manufacturing facilities under accepted QA standards (based on ISO 9000), or certification of products by bodies accredited under EN 45000 and EN 29000 standards in EC member states.

- Mutual recognition of testing and certification may be negotiated in the future and would be enforced by common procedures for regulated products and harmonized standards for quality assurance (EN 29000) and laboratory accreditation (EN 45000). A European Organization for Testing and Certification (EOTC) would coordinate recognition for unregulated products. Recognition agreements could be negotiated by the Commission (regulated products) and by the private sector (unregulated products). Canadian or other non-EC bodies could be subcontracted by a notified body in the EC for some aspects of the testing and certification of regulated products.

- Information about European standardization can be obtained from the Standards Council of Canada, CEN and CENELEC, business contacts, overseas production operations, and agents, customers, or business partners located in the EC.

Trade Implications for Specific Canadian Industries

- Evaluations comment on the following sectors: chemicals; environmental products, equipment, and services; fisheries and food products; forest products; machinery and equipment; meat; minerals and metals; motor vehicles; pharmaceuticals; and telecommunications equipment.

Introduction

Europe 1992 and Technical Barriers to Trade Within the European Community

It is a policy of the European Community (EC) to establish a single internal market by 1992. The elimination of technical barriers to internal trade is a principal objective of that policy. In fact, technical standards, including phytosanitary measures, account for more than half of the 279 legislative initiatives found in the 1985 White Paper of the EC Commission on the completion of the internal market.

Business opinion in the EC has focussed on standards policy as the most important aspect, for them, of the Europe 1992 program. In member states of the EC, national bodies establish various technical standards. The national bodies from EC member states have joint membership with similar bodies from European Free Trade Association (EFTA) countries in such regional European standards organizations as CEN, CENELEC, and ETSI. The regional bodies, in turn, provide active, if not dominant, representation for Europe in international standards organizations such as ISO and IEC.

Shared technical standards have the potential to streamline the production, marketing, and technological adaptation of products. In the EC, this potential has been limited despite a highly developed system for achieving standardization.

Technical Barriers to Canadian Trade with the European Community

The technical standards that have limited the market opportunities and competitiveness of Canadian exporters looking to do business in the EC fall into three categories:

- **Voluntary national standards.** In the EC, member states have typically had vastly different voluntary standards for the same product; and, often, those voluntary standards have been generally accepted in those countries as indispensable conditions of purchase.

- **Technical regulations.** EC member states have each created unique technical regulations based on their differing approaches to issues of public concern—that is, health, safety, and environmental protection.

- **Product testing and certification.** As a result of the differences in technical regulations (see above paragraph), the approach and technical requirements for product testing and certification are different in each member state. And although technical standards are being coordinated within Europe, few arrangements have been made regarding the acceptance of alternative testing and certification regimes.

Elements of the Current EC Policy on Standards

Briefly, the current EC policy on standards consists of four elements:

- mutual recognition of voluntary national standards;
- legislation of "essential" health, safety, and environmental requirements, combined with support for the harmonization of European standards;
- information procedures designed to prevent the emergence of new technical trade barriers; and
- shared procedures and standards for quality assurance and laboratory testing, combined with a European organization to handle mutual recognition of testing and certification regimes.

The complete policy is ambitious, comprehensive, and complex. It involves governments, standards organizations, industry, and other interest groups in Europe and represents a major shift of the responsibility for technical harmonization to non-governmental bodies. It may consolidate control by the EC Commission over the technical regulation of products by member states.

In the new European Organization for Testing and Certification (EOTC), the EFTA countries have already laid the groundwork for virtually complete participation in the new policy. Canada will need to precisely identify the "essential requirements" facing its products under this new policy, to establish contact with the organizations implementing the requirements in EC member countries, and, as the EFTA countries have done, to move towards mutual recognition of testing and certification regimes with the EC.

EC Policy on Standards

Objectives

The EC policy on standards has the following principal objectives:

- **The removal of existing technical barriers to trade between member states.** This objective is to be met through: mutual recognition of voluntary national standards and of testing and certification, and the harmonization of technical regulations (by legislating "essential requirements"). The "essential requirements" will then be incorporated into the European standards being developed by the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI).

- **The prevention of new technical barriers to internal trade.** This objective is to be met through the implementation of extended information procedures that apply when technical regulations are proposed by member states.

- **The encouragement of industrial development within the EC.** This objective is to be met by promoting European standardization. The expected results are improved industrial competitiveness, technological adaptation (e.g., interconnectivity in telecommunications), and government procurement.

Historical Background

EC member states have been accustomed to legislating national policies and technical regulations for products. Article 30 of the Treaty of Rome, which took effect on January 1, 1958, calls for the abolition of technical barriers to trade within the Community. However, under Article 36 of the Treaty, EC member states are still permitted to impose restrictions on imports, exports, or goods in transit, for reasons of health, safety, and environmental protection. In exercising their rights under Article 36, EC member states have been adopting regulatory approaches whose effect has been to prevent the implementation of Article 30.

Early attempts to prevent national standards and technical regulations from limiting intra-Community trade involved:

- challenges before the European Court of Justice, and

- EC legislation, which is enacted under Article 100 of the Treaty of Rome, and which attempts to harmonize the detailed technical requirements found in national standards and technical regulations.

"Old Approach" to Standards

Between 1969 and 1985, the EC adopted more than 200 Directives to harmonize national technical requirements. This "old approach" covered major industrial products (e.g., electrical products and consumer electronics in the Low Voltage Directive of 1970), automobiles (under more than 40 Directives), other motor vehicles and tractors, food products, chemicals, and pharmaceuticals. But legislative harmonization proved to be too slow. Detailed technical specifications were required for each product; delays occurred owing to the need to achieve unanimous support for approval; frequent revisions were required to reflect technological change. Implementation of harmonized requirements was outpaced by the rapid proliferation of new technical regulations enacted by national governments and new voluntary standards created by national standards organizations.

Then, rulings from the European Court of Justice provided the legal basis for a new EC policy on removing technical barriers to internal trade. The most far-reaching was the decision on the Cassis de Dijon case, which in 1979 established the principle of "mutual recognition". This ruling, on the sale of French cassis liquor in Germany, confirmed that, under Article 30 of the Treaty of Rome, a product legally made and sold in a member state could be marketed in any other member state regardless of whether it met the second state's domestic standards. Only where fundamental issues of health, safety, or environmental protection were involved could a product's sale be restrained.

The "mutual recognition" principle was sustained in subsequent rulings of the Court against German regulations on the composition of beer (1987), Italian regulations on pasta (1988), German restrictions on imports of sausages made from soy protein (1990), and Italian marketing regulations on the minimum fat content of cheeses (October 1990).

"New Approach" to Standards

"Mutual recognition" helped to minimize the internal trade problems associated with voluntary national standards—that is, for unregulated products. However, "mutual recognition" could not prevent EC member states from adopting, under Article 36 of the Treaty of Rome, differing health, safety, and environmental regulations—regulations that act as trade barriers. The EC was attempting to resolve these regulations by slow and expensive challenges in the Court of Justice. Then, to avoid the time and expense of legal challenges, the EC decided to harmonize in legislation only the "essential requirements" that products must meet for circulation in all member states. (Under the "mutual recognition" principle noted earlier, non-essential requirements cannot be used to restrict trade.)

To complement mutual recognition of voluntary standards and legislative harmonization of essential requirements, the EC added two more principles:

- the prevention of new barriers to trade by the implementation of extended information procedures that apply to new technical regulations proposed by member states, and
- the mutual recognition of testing and certification regimes.

These four elements constitute the "new approach" to standardization. EC policy on standards also covers work to complete initiatives already in progress under the "old approach" of detailed legislative harmonization of standards for certain products, for example, automobiles.

Tools for Meeting Policy Objectives

Mutual Recognition of Voluntary National Standards

"Mutual recognition" is a key tool of the new EC policy on standards. As discussed on the preceding pages, this principle had been enforced by court rulings under Article 30 of the Treaty of Rome. For trade between member states, Article 30 prohibits measures that directly restrict quantity and measures whose effect is to restrict quantity (i.e., "non-essential" standards).

The effect of mutual recognition is therefore to allow products accepted under the voluntary standards of any member state to be marketed in all other member states without having to meet additional standards. However, mutual recognition applies only to unregulated products.

Harmonization of Technical Regulations

Where regulated products are concerned, Article 36 of the Treaty of Rome permits member states to restrict imports of products that do not meet their national technical regulations for safety, health, and environmental protection. Enforcement of Article 30 therefore requires a different tool if internal trade barriers are to be eliminated. This second tool is "harmonization".

Harmonization is being pursued by:

- legislating EC Directives that establish "essential requirements" for health, safety, and environmental and consumer protection. A product that meets the "essential requirements" may be sold throughout the Community.

- giving Commission mandates and financial support to CEN, CENELEC, and ETSI to develop "European standards". European standards are to incorporate the "essential requirements" of the "new approach" Directives concerning regulated products.

As a result, a product for which a "new approach" Directive exists would meet the "essential requirements" if it complied with the corresponding "European standard". The product could then be offered for sale in all EC member states without having to meet further technical requirements. The EC Commission refers to this approach as the "general reference to standards". The "general reference to standards" is being used not only to harmonize technical regulations concerning health, safety, and environmental protection, but also to standardize other requirements considered to be in the public interest (e.g., consumer protection).

Alternatively, a product that is demonstrated by third-party certification to conform to the "essential requirements" of a "new approach" Directive can also be sold throughout the EC. But, while this option affords access to products made under other than "European standards", the method of demonstrating conformity is more difficult than under the "general reference to standards".

The EC has already adopted most of the "new approach" Directives envisaged under the internal market program. Products affected are:

- toys,
- pressure vessels,
- construction products,
- electromagnetic compatibility,
- machinery,
- personal protective equipment, and
- gas appliances.

Additional Directives are expected on medical devices, instruments for metrology, and telecommunications terminal equipment. See Table A for more information.

Table A Products Regulated Under EC Health, Safety, Environmental, and Consumer Protection Regulations[1]

Product	Implementation Date
Electrical products (LVD)[2]	1970
Toy safety	January 1, 1990
Simple pressure vessels	July 1, 1990
Construction products	June 27, 1991
Electromagnetic compatibility	January 1, 1992
Gas appliances	January 1, 1992
Personal protective equipment	June 1, 1992
Machinery safety	December 31, 1992
Active, implantable electromedical equipment	January 1, 1993
Non-automatic weighing equipment	January 1, 1993
Telecommunications terminal equipment	Proposed

[1] Source: EC Commission, Fifth Report of the Commission to the Council and European Parliament, White Paper on Completion of the Internal Market (Brussels: March 28, 1990)

[2] LVD has been included because it is often considered a model for the "new approach" Directives.

The "new approach" owes its success to the decision to legislate the "essential requirements" at a general level. Guidelines concerning the scope of the Directives call for them to "encompass wide product categories and risk [to health, safety, and environmental protection]".

In fact, the Directives adopted so far have cast the "essential requirements" in such general terms that it is difficult to analyse even their broad implications for Canadian exports. Such analysis is more usefully based on the "European standards" that are being developed to interpret the Directives. Nevertheless, it should be noted that the Single European Act instructs the EC Commission to ensure that proposed Directives "take as a base a high level of consumer protection". Commission officials have suggested that the price to third-country suppliers wishing to benefit from access to the EC market under a single standard is the adjustment to higher standards on their regulated products.

Meanwhile, work proceeds on Directives issued under the "old approach" for harmonizing detailed technical regulations. The "old approach" covers products in the following sectors: motor vehicles, tractors, foodstuffs, chemicals, and pharmaceuticals. For convenience, Table B lists, in broad groups, the products to which the "old approach" applies. These products are covered by a total of 69 Directives, of which 55 have been adopted.

About European Standards

Mandates for harmonization are not limited to the legislation of "new approach" Directives. The EC Commission has also given mandates and money to CEN, CENELEC, and ETSI for the development of "European standards". This support is based on industrial policy, particularly in the matters of new technologies and government procurement.

EC policy envisages an important role for "European standards" in opening government procurement contracts to all member states. Under a Directive adopted in September 1990 (90/531/EEC), government procurement contracts for products and services in the water, energy, transport, and telecommunications sectors must reference European standards. Deviations would be allowed only where:

- conformity with European standards cannot be demonstrated technically;
- European standards would be incompatible with equipment already in use;
- European standards are either inappropriate or outdated; or
- European standards would not be appropriate for a "genuinely innovative project".

At the request of the Commission, CEN and CENELEC have submitted a program of standardization in these sectors that implements the Directive.

The demands on European standards organizations under the EC policy are unprecedented and extensive. For example, the Commission has estimated that, between 1961 and 1982, CEN and CENELEC together adopted 133 fully harmonized European standards. These organizations are now being pressed to produce, by 1992, an estimated 2000 additional standards; ETSI is expected to account for another 300. The magnitude of the demand is the result of the EC push to replace national standards with European standards as quickly as possible.

Table B Products Regulated Under Detailed EC Technical Legislation[1]

Group	Products
Agricultural and forestry	Tractors
Chemicals	Classification and packaging of dangerous preparations
	Cosmetics
	Detergents
	Fertilizers
	Good laboratory practices
	Marketing and use of PCBs, asbestos
Fisheries products	Hygiene requirements for aquaculture
	Hygiene requirements for fishery products
	Hygiene requirements for molluscan shellfish
Food	Emulsifiers
	Extraction solvents
	Extracts
	Flavouring
	Foods for nutritional uses
	Frozen foods
	Fruit juices
	Information on ingredients and alcoholic strength
	Jams
	Preservatives
	Sampling and analysis
	Simulants
	Spirit drinks
Motor vehicles	Automobiles
	Motorcycles
	Trucks
Pharmaceuticals and high technology medicines	

[1] Source: EC Commission, Fifth Report of the Commission to the Council and European Parliament, White Paper on Completion of the Internal Market (Brussels: March 28, 1990)

Concerns have arisen over the time its has taken to develop European standards under EC Commission mandates and over the continuing excess of national versus European standards. As a result, the Commission has issued a consultation paper—discussed later in this report—that contains proposals for addressing the concerns.

Information Procedures to Prevent New Technical Barriers

To provide early warning of standards and technical regulations being proposed in each member state, the EC legislated a Directive (83/189/EEC) concerning information procedures. This Directive has been in place since January 1985. The Directive calls for:

- notification, monitoring, and mutual consultation;
- a pause (if necessary) before proposed standards or regulations are adopted, to consider whether trade would be restricted or harmonization objectives met;
- authority to be given to the EC Commission to issue harmonization mandates for European standards;
- a standing Committee (the so-called 83/189 Committee) that is composed of representatives of the Commission and of member states and whose mandate is to implement the Directive.

As of January 1, 1989 (under EC Directive 88/182/EEC), the information procedures were extended to the agricultural products, foodstuffs, pharmaceuticals, and cosmetics sectors. As a result, these information procedures are the EC's principal instrument for monitoring technical regulations and standards in member states and for screening proposals that are potentially trade restrictive or that are requested for harmonization.

Mutual Recognition of Testing and Certification

The EC policy's concern to ensure mutual recognition of test results, test certificates, and marks of conformity was expressed in an EC Council Resolution (90/C 10/01) on December 21, 1989. The *Global Approach to Conformity Assessment* applies to products regulated under "new approach" Directives and to unregulated products that meet European standards or mutually recognized national standards. It attempts to fill a procedural and institutional vacuum regarding the coordination of European testing and certification.

Currently, such coordination is limited to small, sectoral programs. Examples are:

- the CENELEC Certification Agreement (CCA), which provides for mutual recognition of test reports by laboratories that certify the safety of low-voltage electrical equipment;
- the CENELEC Electronics Components Committee (CECC) and the HAR agreement, which issue European certificates for electronic components and low-voltage cables and cords, respectively; and
- the CEN CENCER system, under which a European mark can replace national marks.

Many new programs are envisaged under the EC Resolution, which is based on a framework (COM(89)209) that was submitted to the EC Council in July 1989. *A Global Approach to Certification and Testing* sets out general guidelines and procedures for assessing conformity with Directives. The principal elements of the framework are:

- **Procedures for assessing conformity with EC regulations.** The procedures are divided into "modules" that can be combined in various ways. The greater the risk involved with the product, the greater the requirement for third-party attestation. The modules range from a manufacturer's declaration of conformity, through quality assurance and type approval, to inspection of individual products (where risk to public health and safety is greatest). The "CE" mark would denote that a product conforms with the "essential requirements" spelled out in EC legislation.

- **Harmonized standards for quality assurance and laboratory practices.** CEN and CENELEC have already adopted the EN 29000 quality assurance standards and the EN 45000 standards for their testing, certification, and accreditation bodies. These standards are based, respectively, on the ISO 9000 standards and the ISO/IEC Guides for testing and certification. EC member states are to notify (i.e., direct) their national testing and certification organizations to meet the requirements of the EC legislation.

- **Establishment of a European organization to coordinate conformity assessment.** In July 1989, the EC concluded a memorandum of agreement (Certif 89/1) with CEN and CENELEC that established a European Organization for Testing and Certification (EOTC). In April 1990, the arrangement was confirmed by the EC, the EFTA, CEN, and CENELEC. The EOTC promotes specific mutual recognition agreements for unregulated products in individual sectors. Membership is open to European testing and certification organizations that meet the EN 45000 standards. Although the use of the EOTC is optional, the EC encourages its use for mutual recognition agreements.

- **Support for developing conformity assessment institutions as needed for the internal market.** This principle includes support for developing systems of calibration and metrology.

- **Mutual recognition agreements with third countries.** Direct recognition of testing and certification performed by a body outside the EC requires that the Commission and the government of the third country negotiate a mutual recognition agreement. The Commission would negotiate such agreements under Article 113 of the Treaty of Rome. The conditions of such an arrangement are to ensure that: the technical competence of the bodies in the third country is demonstrated (e.g., by accreditation under standards equivalent to EN 45000); recognition is limited to results and certifications accepted by the bodies designated in the agreement; recognition is reciprocated (i.e., the third country is to recognize testing and certification by notified European bodies).

From Policy into Practice

The European Community has made considerable progress with the legislation for its standards policy. Most of the Directives proposed in the 1985 White Paper on technical barriers to trade have been adopted. By March 1990, the European Parliament had reached a consensus on more than 80 per cent of the proposals. However, implementation of the legislation has not been as rapid.

As a result, the EC Commission has focussed attention on:

- the slow adoption of EC technical regulations into the national law of member states;
- the limited progress in creating European standards for products regulated by EC Directives; and
- the plan to organize the EOTC, the conditions for using the "CE" mark, and the negotiating mandates required for reaching agreements with third countries on mutual recognition of testing and certification.

Progress in the Areas of Concern

Information Procedures

Notification procedures under the 83/189 Directive appear to be working where technical regulations proposed for industrial and agricultural products are concerned. The Commission has reported that draft technical regulations circulated by member states numbered 319 in 1989 (compared to 15 in 1988), for a total of 937 since 1984. For the most part, the drafts have been used in the chemicals and telecommunications sectors to apply "mutual recognition" and to identify harmonization requirements. It is still not clear, however, whether third countries may obtain information about draft technical regulations under the notification procedures.

In contrast, the information procedures for national standards do not appear to be operating as envisaged. The Green Paper refers to findings that "[national standards] have not been fully applied to support market requirements in the EC".

European Standards

The EC has given CEN, CENELEC, and ETSI mandates to develop European standards for:

- products regulated under "new approach" Directives, and
- products related to new technologies (e.g., telecommunications, information technology, and advanced industrial materials).

In addition, the EC Commission has asked CEN and CENELEC to prepare a standards program for government procurement in the transport, energy, water, and telecommunications sectors.

The resulting workload is heavy and unprecedented, and progress by the European standards organizations has been slow. The EC Commission estimates that 800 European standards have been adopted in the six years from 1984 to 1990 and that more than another 800 are required by the end of 1992. As a result, on October 8, 1990, the Commission released a Green Paper entitled *The Development of European Standardization: Action for Faster Technological Integration in Europe*.

The Green Paper contains proposals for greater participation by the private sector, for efficiency, for self-funding, for new organizational structures, and for international cooperation in the creation of European standards. Specific proposals are:

- the establishment of a European Standards System directed by a European Standards Council and managed by a European Standards Board consisting of representatives from CEN, CENELEC, and ETSI;
- a change to majority from consensus voting, to expedite standards development;
- a change to shorter public enquiry periods on drafts (two months);
- direct use of European standards (adoption by national standards bodies not required); and
- the transfer of existing certification agreements operated by CEN and CENELEC to EOTC.

The Green Paper proposes increased involvement for ISO and IEC representatives in the creation of European standards. This involvement could result in improved transparency and responsiveness to global, rather than to regional, interests. International participation could also assist the EC in meeting its commitment to use existing international standards for the internal market.

Testing and Certification

Testing and certification is the area where the most remains to be done. As discussed earlier, "modules" for the assessment of the conformity of regulated products and shared standards for quality assurance and laboratory accreditation have already been adopted. Key elements still outstanding are:

- organization of the EOTC;
- specification of the conditions for using the "CE" mark;
- provision of mandates for negotiating mutual recognition agreements with third countries on regulated products; and
- establishment of accreditation systems in member states and notification of accredited testing and certification bodies.

EC Policy and Third Countries

EFTA Countries

Organizations in the EC and those in EFTA countries (Austria, Finland, Iceland, Norway, Sweden, and Switzerland) have a long history of cooperation on standardization. EFTA countries participate directly in European standardization through their membership in CEN/CENELEC. And the EC-EFTA relationship has further strengthened since the 1985 inception of the EC internal market program. The market access to the EC already enjoyed by EFTA countries is only likely to improve.

In a statement known as the Luxembourg Declaration—adopted on April 9, 1984, at the ministerial level by the EFTA countries and the European Community and its member states—orientations were established for, among other things, future EFTA-EC cooperation. The aim was to improve the free circulation of industrial goods, and one of the priority areas for cooperation was the elimination of technical barriers to trade through harmonization of standards.

EFTA countries have agreements with the EC that relate to two elements of the new policy on standards, namely, harmonization of voluntary standards, and the information procedures for preventing standards and technical regulations to be used as trade barriers. In regard to harmonization, a framework contract was adopted on January 28, 1986, that permits the EFTA to issue standardization mandates, such as those provided by the EC, to CEN and CENELEC.

The EC information procedures on proposed national standards (Directive 83/189/EEC) have been applied by EFTA countries since the procedure became effective in 1985. And on December 19, 1989, the EC and the EFTA signed an agreement for exchange of information on technical regulations. This agreement was adopted by the EC Council on September 24, 1990 (90/518/EEC). It contains procedures similar to those found in Directive 83/189/EEC.

The EFTA countries are showing continuing interest in negotiating agreements for mutual recognition of testing and certification with the EC. As a step in this direction, the EFTA countries recently concluded, under the Tampere Convention, an agreement among themselves for mutual recognition of test results and proofs of conformity.

Mutual Recognition of Testing and Certification

To conclude agreements with third countries for mutual recognition of testing and certification, the EC Commission requires negotiating mandates from the EC Council. The Commission has not yet requested such mandates. Also, any agreements negotiated by the Commission would cover only regulated products; other products would be handled in private-sector agreements.

However, third-party test results for regulated products might be recognized indirectly should a notified body in Europe subcontract testing to the extent allowed by the EN 45000 standards. Subcontracting is permitted to cover only some of the required tests; the European body would remain responsible for the test results and would, itself, have to provide the certification. The European body would also be responsible for keeping records of the subcontracts and for ensuring that the testing body in the third country meets the EN 45000 standards.

EC Policy and Canadian Trade Interests

While the new EC policy on standards applies to industrial products in general, the EC Commission has cited foodstuffs, information technology, telecommunications, and construction and building products as priority sectors. The importance of Canadian trade with the Community in these sectors underlines the broad significance of the EC policy for Canadian industry.

The EC is Canada's largest overseas export market. In 1989, exports from Canada to the EC amounted to $11.3 billion. Wood pulp made up 15 per cent of all Canadian exports to the Community, while softwood lumber accounted for 7 per cent. Other Canadian exports to the EC included fish and fish products, newsprint, computers, nickel, iron ore, and aircraft and aircraft parts. In the same year, imports from the EC amounted to $14.5 billion.

Canadian exports to the EC, particularly fish products, value-added forest products, non-ferrous metals, and petrochemicals, face high tariffs, import quotas, technical restrictions, and other non-tariff trade barriers. Any assessment of the trade implications of the new EC standards policy must take these factors into account. Moreover, as noted previously, competing exporters in EFTA countries, who already have duty-free access to the EC, may benefit from the expanding cooperation on standards between the EFTA and the EC.

Traditional differences between European and Canadian standards are not likely to disappear as a result of the EC policy. European standards for electrical products, for example, have evolved differently from those in North America partly owing to differences in power grids and regulatory approaches. The experience in telecommunications has been similar, although there is now an emphasis on interconnectivity of networks. Road traffic systems—such as left-hand drive in the U.K.—have dictated differences in motor vehicle standards. Construction standards often reflect experience with using indigenous building materials. (For the same reasons, standards and regulatory regimes have differed among European countries.)

Harmonization offers an opportunity to market Canadian products throughout the EC, provided the products are accepted under the standards or technical regulations of one member state. This opportunity exists regardless of whether the relevant European standards or regulations differ from those in Canada. Harmonization therefore affords exporters the opportunity to produce to different standards for a larger market. By selling to the EC as a whole, Canadian suppliers can avoid the costs of having separate supply systems for individual member states and could realize economies of scale in manufacturing and distribution. Companies with operations or business arrangements in the EC stand to benefit most should the EC policy succeed, but the benefits need not be exclusively theirs. Many Canadian firms stand to gain.

However, the advantages of the harmonized internal market are not likely, in practice, to be generally available on January 1, 1993. As indicated earlier in this report, more time will be required to complete the new standards and the testing and certification agreements. And despite "mutual recognition", consumer preferences in the EC for products made to voluntary national standards will remain to be overcome. Furthermore, some representatives of Canadian industry have noted that deft handling of differences in language, customs, and local business practice is often more important to successful business operations in Europe than is meeting certain standards.

Regulatory Coverage of Canadian Exports

Market access for Canadian exports under the new EC policy will chiefly depend on the particular "essential requirements" that apply to each product. Equally important will be the rules for demonstrating conformity with the requirements. To repeat: All products regulated under EC harmonization Directives ("new" and "old" approach) and products referenced for government procurement will have to meet certain "essential requirements". Tables A and B list the product sectors covered by Directives.

Some representatives of Canadian industry, particularly those in the machinery and equipment sector, are concerned that the Directives do not describe the specific products to which they apply. In particular, the Directives on government procurement refer only to the broad sectors covered by procurement contracts (e.g., water, transport). The related "European standards" for regulated products are intended to provide greater detail, but, in most cases drafts are only just beginning to become available from CEN, CENELEC, and ETSI.

Use of International Standards

Officials of the EC Commission have indicated that "European standards" will be based on international standards wherever possible. In cases where international standards do not exist, the European standards developed will be later submitted as proposed drafts for ISO and IEC standards. The recent Green Paper took a further step by proposing that representatives of international standards organizations participate directly in CEN and CENELEC technical committees.

Since early 1989, CEN and CENELEC have been working with ISO and IEC to exchange progress reports and information about programs and other standards activities. In addition, to expedite work on standards, the IEC-CENELEC agreement provides for parallel voting procedures. In February 1990, it was estimated that about 85 per cent of CENELEC standards were adopted from IEC.

It has been suggested, however, that, in the information technology and telecommunications sectors, international standards may not be fully available in time to meet EC requirements for the internal market. In fact, the ISO/IEC Joint Technical Committee No.1 (JTC1) on Information Technology has made rapid progress since its establishment in 1987. Canadian companies may make representations concerning international standards to ISO and IEC through the SSC. Such representations will be used to formulate Canadian positions for those international forums.

Testing and Certification

A major concern of Canadian companies is to ensure that their products have ready access to testing and certification so that the products will be accepted under EC Directives or the corresponding European standards. Canadian exports produced to meet the harmonized technical requirements of the EC must, of course, demonstrate conformity with those requirements.

In principle, the choice of methods for establishing a product's conformity with EC Directives should be the same for both Canadian suppliers and suppliers in the EC. And, indeed, the EC has affirmed its intent to provide non-discriminatory treatment regarding testing and certification of products from third countries. Many Directives allow manufacturers simply to declare their product's conformity with the "essential requirements" as reflected in European standards. They then apply the "CE" mark and keep the supporting technical documentation on file. Canadian exporters choosing this method would have to provide the supporting documentation to their agents or importers in EC member states.

Canadian products that are not manufactured to European standards require certification by bodies accredited under EN 45000 standards in EC member states. Products that fall under more stringent requirements—for example, wood-working machinery or medical devices—require either that the manufacturing facilities be registered under EN 29000 quality assurance standards (with surveillance by a notified body) or that the product be given type approval by a notified body before it is marked.

Compliance with EN 29000 quality assurance standards, which are based on ISO 9000 standards, is therefore important for Canadian manufacturers. Compliance not only helps to gain acceptance under EC requirements but also assists in meeting the requirements of consumers and procurement authorities in many countries.

Registration under the necessary quality assurance standards has already begun to grow in Canada. The Quality Management Institute (QMI) of the Canadian Standards Association (CSA) and the Canadian General Standards Board (CGSB) provide such registration. For example, Northern Telecom recently registered its telecommunications switching equipment plant in Brampton, Ontario, through QMI. In a related development, the Standards Council of Canada is considering the establishment of a national accreditation system for bodies registering quality management systems.

Testing and certification of Canadian products for acceptance in the EC could also occur under mutual recognition agreements. As noted earlier, the technical competence of the bodies to be accredited is a decisive factor. The EC has indicated that accreditation under similar standards would be an advantage. Currently, nationally accredited testing and certification bodies are members of the National Standards System (NSS), which is coordinated by the SCC. The NSS could provide a framework for mutual recognition agreements. The NSS is currently composed of 6 accredited bodies for certification and more than 30 for testing. Given the role of quality assurance in the EC policy on standards, the national accreditation system being envisioned by the SCC could, if adopted, further facilitate mutual recognition agreements with the EC.

Some Canadian companies have their own agreements on certification and testing with organizations in some EC member states. In all provinces, associations representing forest industries are approved for certification of grading rules under standards that apply to lumber imports to the United Kingdom (British Standards Institution (BSI) and others). The Canadian Standards Association has agreements with BSI and KEMA for the recognition of the testing and certification of electrical and other products. To the extent that these other agreements already provide recognition for products regulated in the EC, it will be important to ensure that this recognition is maintained under the new policy.

Obtaining Information on European Standardization

For products regulated under EC Directives, information about, and assessment of, draft "European standards" are key to determining the specific technical requirements that Canadian products will have to meet for circulation in the EC.

Under a contract with the Standards Council of Canada (SCC), External Affairs and International Trade Canada have provided financial support for establishing a system that makes timely information on "European standards" and on certification and testing requirements available to Canadian business. The information system established by the SCC makes draft standards and other European standards activities available to Canadian businesses and interest groups on request. A monthly publication entitled *Europe '92 Trade Winds* was launched by the SCC in July 1990. (A sample copy is attached to this report as an annex.)

Transparency procedures adopted by CEN and CENELEC during 1989, at the request of the EC Commission, have made it simpler to gather useful information. The transparency procedures include:

- publishing, since 1989, a monthly review of CEN and CENELEC activities. Work programs and the status of draft standards are reviewed.

- making draft standards from CEN and CENELEC available on request when they are released in Europe for the 60-day public enquiry period that precedes their adoption.

- having the technical committees of CEN and CENELEC consider comments received before the end of the public enquiry period through member bodies of ISO and IEC regarding draft standards. (Because the Standards Council of Canada is a member body of ISO and IEC, the Council is in a position to operate this cooperative arrangement.)

In addition, representatives of Canadian industry have access to draft European standards through their own business contacts. Furthermore, companies with production operations in Europe have direct access to the committees that represent national standards organizations in CEN and CENELEC. Other companies have indirect access through their agents, their customers, or their business partners in EC member states. For example, Canadian companies in the wood products, telecommunications, and pharmaceutical sectors have been using these means to follow the development of European standards.

Trade Implications for Specific Canadian Industries

EC standards policy will be applied to individual products under specific Directives, under CEN, CENELEC, or ETSI standards, and under the procedures of notified testing and certification bodies for conformity assessment. In addition, sectoral agreements for testing and certification of non-regulated products under EOTC or agreements to be negotiated by the Commission with third countries for regulated products will be elements of the EC policy. Analysis of how Canadian products may be affected is limited to those products for which draft European standards are available, as the "new approach" Directives contain few specifics. Information concerning testing and certification for specific products is virtually unavailable at present, except where included in Directives.

For these reasons, this section is simply a progress report on individual sectors of interest to Canadian exporters. The focus is on regulatory, industrial development, and government procurement issues raised by the EC standards policy. This section, which has been prepared by sector specialists from the Working Group on Standards, Testing, and Certification, is intended to complement the reports of other sectoral Working Groups of the Federal Task Force on Europe 1992.

Chemicals

The EC is an important export market for Canadian chemical companies. In 1989, exports to the EC of chemicals and chemical products—including uranium—totalled $607 million, making the EC Canada's third most important foreign market in this sector. Five chemical products (i.e., styrene, polyethylene, vinyl acetate, methanol, and isopropyl alcohol) accounted for more than 35 per cent of all sales.

The EC has addressed harmonization of standards in the chemicals sector largely with "old approach" Directives. As previously noted in this report, this approach to technical harmonization is often slow, and Directives must be regularly revised to incorporate new or more stringent standards. Many Directives have already been implemented, covering such products and processes as: detergents, extraction solvents, fertilizers, the handling of toxic waste products, the registration and certification of certain pesticides, and the marketing, packaging, and labelling of dangerous substances.

In general terms, EC initiatives to harmonize various regulations affecting the chemical sector have been viewed as beneficial to the entire industry. Standardization initiatives eliminate the divergent national standards that make it difficult for smaller firms to market a product in more than one country.

Some concern has been expressed, however, concerning EC initiatives in environmental and public safety regulations. These initiatives, often driven by environmental organizations, may cause European standards to fall out of step with North American regulations. The resulting standards and regulations could be trade discriminatory, making it more difficult both to penetrate and to maintain European markets. Furthermore, member nations of the EC have the flexibility to set or to impose certain restrictions on specific chemicals and chemical products after notifying the EC Commission. While the EC retains the powers necessary to set certain minimum standards, individual countries can impose additional restrictions, unique to their country, once they have notified the Commission of the reasons for such an action.

To summarize: While certain Directives may be of particular concern to sub-sectors within the chemicals sector, the overall impact is expected to be minimal, largely owing to the concentration of Canadian exports into a small number of commodity classes. Many observers believe that certain key advantages under the Europe 1992 initiative outweigh specific concerns and will result in actual savings. These advantages—which include standardized packaging and labelling regulations, simplified cross-border trade and Customs procedures, and the proposed deregulation of transportation within the Community—are seen as a viable means to reduce costs, thereby improving competitive position.

Environmental Products, Equipment, and Services

Because of the strength of the Green Movement in Europe, the EC can be expected to develop standards to regulate this important and burgeoning sector. No directive has yet been put forward by the Community, however.

Canada is among the world leaders in this field. The Task Force believes that Canada and the EC should work with other countries to develop international standards in environmentally-sensitive fields, ensuring that products are not precluded from each other's markets owing either to technical regulations or to lack of competitiveness when environmental costs are added to production costs.

Fisheries and Food Products

The EC purchases approximately 12 per cent of Canada's exports of food and beverages. In 1988, exports amounted to about $750 million and were largely composed of fish and red meats in addition to the traditional exports of such specialty products as honey, maple syrup, and frozen blueberries.

The EC market is difficult to enter. The problem has less to do with standards than with the variable levy system, which prices most primary agricultural imports out of the market and with preferential tariff and quota arrangements and a multi-tiered, protectionist import regime for fisheries products. For those products that Canada is successful in exporting to the Community, harmonization of national standards and further integration of the European market could be beneficial.

Nevertheless, the EC move toward a single internal market presents several challenges to countries outside the EC. The Canadian agri-food sector will be particularly concerned about:

- how the Europe 1992 initiative will influence access and competition in those markets where Canadian foods are established;
- what new technical requirements the EC legislation may create, necessitating adjustments to Canadian shipping, processing, and inspection practices; and
- whether the EC might adopt health and sanitary requirements that differ from accepted international norms.

Work will be required to create improved and secure access for Canadian food products to the EC member states. Where possible, compatible legislation and regulations should be developed for North America and Europe, using *Codex Alimentarius* as the basis of this international harmonization.

Where food legislation is concerned, EC member states have reached agreement-in-principle on the mutual recognition of national standards. Apparently, however, no decisions have yet been taken as to how the EC will handle third-country food imports. Information is lacking regarding if, when, or how the EC Commission intends to negotiate mutual recognition agreements with governments of third countries for regulated products (including food).

In the matter of unregulated manufactured goods, the EC envisages an increased role for the private sector in the testing and certification of products. In Canada, the government is primarily responsible for certification; it performs tests that are meant to ensure public confidence in the healthfulness, safety, and quality of the food supply. Until more is known about the proposed role of the European Commission in testing and certification of these products, further assessment of the implications for this particular sector is difficult. However, by examining the modular approach enunciated in the EC Global Certification and Testing Policy, some insight might be obtained about practices that could possibly be expanded to cover regulated products such as food.

Forest Products

Exports from the forest products sector lead Canadian exports to the EC. Forest products account for $3.5 billion in exports, approximately 31 per cent of all exports from Canada to the EC. The EC is Canada's second-largest export market for forest products (after the United States). In 1989, exports of wood pulp, newsprint, and other paper and paperboard to the EC represented $2.7 billion in sales. Wood products such as softwood lumber, plywood, and hardwood lumber totalled $881 million in the same year.

To date, the most important EC initiative involving this sector is the "new approach" Construction Products Directive, which is scheduled for implementation in mid-1991. This Directive is intended to remove internal barriers affecting construction materials and products by setting one standard for most construction materials. Besides materials such as concrete, masonry, steel, and installations and equipment used in construction and civil engineering works, the "construction materials" category includes various wood products and is therefore of concern to Canadian suppliers of forest products. The Directive outlines six key requirements that must be met by all construction projects and by all products used in the structure. Further, the Directive authorizes the development of European technical specifications, harmonized product standards, and European technical approvals.

CEN has been directed by the EC Commission to draft the necessary standards. CEN has also been charged with the responsibility for developing common standards for building codes. Standardized European building codes—as expressed in Eurocodes 1 through 8—are important to Canadian suppliers of forest products because these codes contain standards for various types of construction and uniform safety requirements. Eurocode 5 is especially important; its *Common Unified Rules for Timber Structures* include product and testing standards for wood.

The effect of all of these standardization efforts on Canadian interests are being monitored closely. From the reviews so far conducted by both the private sector and the public sector, it appears that Canadian producers should experience no particular difficulty in meeting the proposed standards. Moreover, Canadian industry stands to gain, as the adoption of uniform standards is expected to lead to unified product standards for the member states of both the EC and the EFTA. (EFTA members formally participate in European standards organizations).

Another (proposed) Directive entitled *Material and Articles in Contact with Food* deals with materials that come into direct contact with foodstuffs or water. Provisions in this directive will affect suppliers of food-packaging materials. Canadian producers of paper and paperboard products that are used in food packaging will have to take account of these EC standards to ensure continued access to this market. Producers of other food-packaging materials (i.e, plastic, glass, metals, and rubber) will also have to take note of this Directive.

Machinery and Equipment

The machinery and equipment sector includes a wide range of heavy machines and equipment for resource extraction and processing, for manufacturing and service industries, and for industries that generate power or that manufacture electrical equipment or major appliances. Canada exports about 30 per cent of its total production, and 80 per cent of those exports go to the United States. About 5 per cent of Canada's exports in this sector go to the European Community; by contrast, about 15 per cent of Canadian imports in this sector come from the EC. Approximately 250 Canadian companies, including some subsidiaries of foreign-owned firms, export to the EC, but only 20 Canadian-owned businesses have subsidiaries operating there. Of the 20, 13 have office and warehouse operations in Europe. These companies are certain to be recognized as domestic suppliers to the EC after 1993, but expanded trading rights have not yet been clarified.

To remain competitive in world markets, increasing numbers of Canadian manufacturers in this sector are specializing. A company may concentrate on producing certain sizes or types of machines or may make custom-engineered products. This group includes producers of forest-harvesting equipment and of machinery for working plastic and rubber. The ability to service a specific market niche allows these companies to compete in export trade; they are unlikely to be much affected by Europe 1992.

To further illustrate the point that the EC market for Canadian manufacturers in this sector will not be adversely affected after 1993, it should be noted that EC standards will be inherent in any order from an EC customer for custom-engineered machinery. Consequently, when the Canadian firm accepts the order, it will do so in the full realization that it can meet the EC standards set for that particular piece of machinery.

It should be pointed out, however, that if specific product qualification or certification to European standards is a prerequisite, there may be some impediment and certainly some added cost if the certification or qualification can only be undertaken in facilities located in an EC member state. A system of mutual acceptance of test data by certification bodies would overcome this problem.

Meat

Harmonization of the EC's meat standards in the meat products sector is aiming to replace border control inspections with inspections at the site of production. Where product quality is concerned, the emphasis is therefore shifting from reliance on final-product testing to reliance on quality control and quality assurance methods. The associated responsibility is shifted to the industry, which is expected to self-regulate in the area of quality.

All of these changes are based on a Directive that sets out standards for facilities and inspection of the meat being traded on the internal market. Although the Directive has been in place for several years, its terms were ignored by many member states, who continued to operate according to national standards. Brussels has now instituted a plant review program, and there is evidence of increasing compliance.

Canadian firms that want to export meat to the EC have to meet the requirements of the EC third-country Directives for meat plants. If the firm's system of inspection is to be recognized, a residue-detection plan based on an approved methodology has to be provided to the EC annually. Such an arrangement presupposes an agreement by the EC that the labs used by Agriculture Canada are equivalent to theirs and that standardized international methodologies are employed in the labs. Currently, Canada has had 12 slaughter plants, 3 cutting plants, and 11 storage facilities approved by the EC.

The EC now has full authority, on behalf of member states, to negotiate EC market access for meat products with foreign countries. Nevertheless, the accreditation of laboratories may have to be undertaken on a more formal basis through a negotiated protocol.

The use of internationally agreed-upon standards—such as ISO—can only be beneficial for Canada, as most Canadian sampling plans have been derived from ISO sampling plans.

Notice, however, that the foregoing discussion applies only to fresh and frozen red meat. Poultry and processed meat products are still not handled directly by the EC. Approvals of Canadian plants are still performed by member states and are limited to those states, with no mutual recognition by other states. Approvals are based on intra-Community Directives for these products.

For several years now, there has been talk of implementating third-country Directives and EC review for both poultry and processed meat products. There is still no clear indication of when such action is likely.

Minerals and Metals

The value of Canada's exports of minerals and metals to the EC is second only to that of exports of forest products. In 1988, Canada was the fourth-largest supplier of minerals and metals to the EC, accounting for sales of approximately $3.1 billion. The exports mostly consist of basic mineral products, including iron ore, zinc, copper, nickel, asbestos, titanium slag, and lead. Metal exports include aluminum, gold, platinum, refined copper, and some primary iron and steel products.

The Europe 1992 drive has largely excluded the minerals and metals industries, mainly because minerals and metals are not normally subject to standards, testing, and certification. Only a very few of current EC Directives have any bearing on the minerals and metals sectors, and those Directives are chiefly concerned with environmental and health protection rather than with standards issues. These Directives specify the handling and use of a wide variety of minerals, metals, and related products largely because of their apparent carcinogenic properties. Current regulations cover a variety of minerals and metals, including asbestos, cadmium, lead, nickel, and titanium dioxide. The regulations range from prohibitions on the use of some minerals in specific products (e.g., a prohibition on the use of asbestos in defined products), through limitations on the disposal of hazardous waste (e.g., prohibitions on the discharge, disposal, and transport of hazardous goods, including lead and mercury), to product-specific guidelines that affect distinct products (e.g., regulations concerning the controlled disposal of batteries containing cadmium, lead, and mercury).

In general, the Directives proposed for Europe 1992 are not expected to have a major impact on the export of raw materials in the minerals and metals sectors. Regulations will, however, pose implications for the trade in processed products, particularly where the mineral or metal has been associated with an environmental or health concern. To ensure their continuing access both to the EC and to other world markets, Canadian companies will have to take account of new measures that relate to the environment and to health and safety concerns.

Motor Vehicles

Since 1970, the EC has adopted more than 50 measures harmonizing technical standards and type approval for motor vehicle components. As a result, a car approved in one member state can normally be marketed in another without further approval.

Just three standards remain unadopted: those concerning tires, safety glass, and weights and dimensions. Adoption of these standards has been blocked by France (with the tacit support of other member states) for more than ten years.

An "effective" European type approval may not materialize until agreement has been reached on a common commercial policy for the industry: that is, a solution for controlling imports of Japanese cars. Some European auto makers (notably the French) fear that their overseas competitors would reap the greatest cost savings from full harmonization and argue that completion of a European type approval should be delayed until EC cars have significantly penetrated the Japanese market (reciprocity).

Even after European type approval is achieved, some of the conflicting national standards could survive, as member states are allowed to maintain national standards in their domestic markets in parallel with the EC standards. A Canadian exporter may then face a choice of standards in a given market.

Economics

Economies of scale are expected in the car industry owing to the widespread rationalization of "platforms" based on designs shared by different manufacturers. The demand for larger quantities of identical components should result in a lower overall vehicle cost (estimated to be about 5 per cent).

The need to conform to divergent technical regulations discourages parallel imports to take advantage of the sizeable price differentials between car markets. These differentials are caused partly by artificially differentiated markets and partly by differing value-added taxes (VAT); they are enforced by protectionist standards. National technical certification procedures help to control compliance with the national quantitative restraints that Italy, Spain, France, and the United Kingdom apply to Japanese automobiles.

Implications for Canadian Trade and Investment Relations

Canadian companies that are interested in the European market will want to monitor three developments: type approval measures, third-country automotive treatment, and mutual recognition of testing and certification.

Europe has not traditionally been a large export market for Canadian vehicles or parts. Essentially, Canadian manufacturers are interested in preserving preferred access to the North American market. With a few notable exceptions, these manufacturers are not established in Europe, and many are not entitled to sell there owing to restrictions by a parent company. The larger integrated vehicle manufacturers established in Canada closely monitor EC developments concerning standards, regulations, and other potential trade barriers.

At present, North American products can be modified for testing and certification by one of the qualified European testing organizations. It is essentially a question of economics whether Canadian manufacturers decide to absorb the costs of producing Canadian products to meet European standards or, conversely, adapt to them only as required on a model-by-model basis.

Chrysler Canada is the only major vehicle exporter to Europe. Modifications to meet European national standards are controlled by Chrysler U.S.A. and are performed in the U.S. for vehicles assembled in either the U.S. or Canada.

Pharmaceuticals

Within the EC, the pharmaceutical industry is subject to a high degree of government regulation. The admission of new products to national markets is strictly controlled. Proof of safety, effectiveness, and quality is universally required. The necessary regulation occurs on a national basis, although with a considerable degree of uniformity, owing to the various Directives issued by the EC Commission since 1965. But while much progress has been made in establishing the basis for a common approach to pharmaceuticals within the EC, it is questionable whether that approach is workable, with the possible exception of administrative procedures.

Among other things, the European Council has adopted Directives on:

- pharmaceuticals pricing transparency, whose aim is to make procedures for granting marketing authorizations and for admitting pharmaceuticals to social security reimbursement schemes more open; and

- biotechnology and high-tech goods, which call for a coordinated procedure at the EC level to examine the authority to merchandise the products in the EC.

A key Directive that is currently awaiting adoption focusses on biotechnological inventions. This Directive seeks to harmonize patent protection for biotechnological inventions throughout the EC, thereby providing the legal certainty that industries require to develop products in the biotechnological field.

It is too soon to make a definitive judgement on how the Community's initiatives in this area will affect Canadian exporters. The significant presence of multinational enterprises (MNEs) could have a dampening effect on the potential for increased exports to the EC by Canada's domestic brand-name pharmaceutical industry. In contrast, however, given the greater acceptance, worldwide, of "generic" drugs, export opportunities may well increase for drugs of this type as well as for biologicals and diagnostics.

Within the EC, the preferred response to the "single market" appears to be an intense and rapid rise in merger and acquisition activity by non-EC suppliers. By forming joint ventures or partnerships with existing EC firms, these suppliers are attempting to obtain and to guarantee access to the EC market.

Telecommunications Equipment

To remove technical barriers to trade in telecommunications equipment and to ensure that the European telecommunications infrastructures serves European industry well, the EC has taken a number of initiatives on standards. These initiatives embody the dual approaches of "mutual recognition" (with certification where appropriate) and the harmonization of technical regulations and specifications where necessary or where standards do not currently exist.

The intent of the initiatives is to ensure that the supply of terminal equipment is not a monopoly of the public networks. Private suppliers from any member state are to be able to pursue this business. It is intended that procurement opportunities be open to all companies within the Community—that is, PTTs will no longer be able to ensure that a contract goes to a local supplier by demanding that a particular national standard be met. Furthermore, value-added suppliers are intended to have access to the networks in such a way that a true market in services is created.

Telecommunications Terminals

Regarding the certification of terminals for connection to the public networks, the EC Council adopted a Directive in 1986 (86/361, as published in OJL217/86) requiring that certification bodies in member states recognize, for certification procedures, the results of tests performed in other member states. In a second phase of this action, the EC Commission has proposed a Directive that would require mutual recognition of test certificates. That is, once certified for use with the public network in one member state, a product would automatically be recognized for use with the public networks of all member states.

It is anticipated that ETSI will develop a common European standard for terminals (see next subsection). In the interim, however, approvals will be based on national standards. But national authorities can demand only that products meet certain "essential requirements" with regard to electrical safety (which simply requires a manufacturer's declaration under the Low Voltage Directive), electro-magnetic compatibility (which requires third-party testing), no harm to the network (either physical or logical), and interoperability in justified cases (end-to-end operability).

European Telecommunications Standards Institute

To encourage telecommunications standardization, the EC Commission has encouraged the establishment of the European Telecommunications Standards Institute (ETSI) and has recognized it as the European focus for developing appropriate standards. Like CEN and CENELEC, ETSI will receive mandates from the Commission to develop certain standards.

ETSI has been established as an autonomous body (i.e., not a PTT monopoly) whose members are national administrations (regulators and licence grantors), network operators, manufacturers, users, value-added service providers, and research bodies. The organization is also open to observers from EC and EFTA countries, and representatives of third countries may attend plenary sessions of the Institute as "special guests". "Special guests" will not, however, have access to the technical committees.

ETSI has a support staff of about 50, which is paid for by the members, each contributing according to ability to pay.

ETSI is to produce European telecommunications standards in telecommunications, in information technology (in cooperation with CEN and CENELEC),and in broadcasting (in cooperation with the European Broadcasting Union). The European telecommunications standards are to be produced based on a system of weighted voting, world-wide enquiry, standstill on national standardization (once ETSI has begun to deal with an issue), and obligatory transposition into national standards once agreed.

Integrated Services Data Network

By way of an EC Council recommendation (86/659 OJL382/86), member states have agreed to the coordinated introduction, by 1992, of the Integrated Services Data Network (ISDN). This recommendation was formalized by a Memorandum of Understanding, which signed in April 1989 by 22 telecommunications administrations in the 18 EC and EFTA countries. The Commission followed up the Memorandum by giving ISDN, in June 1989, a mandate to undertake standardization work. ISDN is to have an open network provision.

By way of an EC Council recommendation and directive (87/371 and 87/372, OJL96/87), member states have agreed to the introduction of a pan-European mobile telephone system. The Commission expects that a Memorandum of Understanding for the introduction of the system will be signed by the middle of 1991, with the first commercial operations starting about that time. The standardization work will likely be given to ETSI.

Although the impact is not immediate, the development of European telecommunications standards under the auspices of ETSI will continue to be of utmost importance to Canadian manufacturers in the sector. In parallel with the transparency measures for the CEN and CENELEC process (see page 24), the SCC is making arrangements with ETSI to secure access to draft standards for review and comment.

EUROPE '92

TRADE WINDS

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Close up: EC Directive on Active Implantable Medical Devices

The European Community's (EC) Active Implantable Medical Devices Directive (90/385/EEC) will become effective January 1, 1993, covering active (powered) implantable medical devices such as cardiac pacemakers and defibrillators, neural stimulators, and drug infusion devices.

Active implantable medical devices are defined by the directive as any instrument, apparatus, appliance, material or other article, used alone or with accessories or software, intended for use by human beings in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury; the investigation, replacement or modification of the anatomy or of a physiological process; or the control of conception.

The definition specifies that the devices may be assisted by pharmacological, chemical, immunological or metabolic means, but do not achieve their "principal intended action" by these means. The devices must rely on electrical energy or a source of power other than the human body or gravity. They must be intended to be totally or partially introduced, surgically or medically, into the human body and intended to remain there.

The directive's essential requirements state that these powered implantable medical devices must safeguard the clinical condition and safety of patients, and they must not present any risk to others. The devices must meet safety and efficacy requirements in their design, construction and materials used.

Following an EC type-examination (to establish that they satisfy the directive's requirements), products must bear the "CE" mark in order to be acceptable for distribution throughout the EC and instructions must be provided with the device. In addition, products must be subject to a quality system involving periodic inspections to ensure that they continue meeting requirements.

Further information on the Active Implantable Medical Devices Directive and a listing of European standards it encompasses is available on request from the Standards Council of Canada.

Seminar examines changing rules for selling in Europe

Canadian manufacturers are assured access to Europe's Single Market, says Roger Brockway of the Commission of the European Communities, one of several experts who participated in a seminar entitled *The Rules are Changing -- Standards and Europe 1992*.

In the regulated market, access for non-European products is secured by legislation. In the non-regulated market, he says, "the Community will not interfere in commercial mutual recognition or subcontracting agreements."

The seminar, held December 4, 1990 in Toronto, attracted some 150 business professionals. It was jointly sponsored by External Affairs and International Trade Canada, Ontario's Ministry of Industry, Trade and Technology, the Standards Council of Canada, and the Canadian Exporters' Association.

Under the New Approach to standardization, the Commission of the European Communities issues directives for specific product groups, outlining minimum requirements that must be met before products can circulate freely throughout the EC. Directives already in force (or soon to be) cover toy safety, simple pressure vessels, construction products, electromagnetic compatibility, machine safety, personal protective equipment, non-automatic weighing machines, active implantable medical devices, gas appliances and telecom terminals.

Canadian manufacturers shipping to Europe should identify what directives affect their products, and what standards must be met to satisfy the directives' requirements, says John Kean, President of the Canadian Standards Association. They must also determine what kind of conformity assessment is required.

he added.

However, meeting the essential requirements may not be enough, he warns. Additional demands may be imposed by large organizations and institutions, requiring that additional standards be met or that a product bear the certification mark of the country in which it will be sold.

Keynote speaker Roy Phillips, President of the International Organization for Standardization, emphasized the importance that international standards now hold for Canada. Europe, he said, is going international, and by 1993 will have far more standards based on international standards than any country or region outside Europe.

"It would be a mistake for Canada not to proceed on this basis, and I would urge Canada to embrace international standards

DRAFT EUROPEAN STANDARDS

In cooperation with CEN and CENELEC, the Standards Council has developed procedures by which Canadian industry can obtain draft European standards for review, provide input into these draft standards, and purchase published European standards.

Information on CEN/CENELEC draft standards (prEN) that are presently in the comment stage of development is listed below. Copies of these drafts may be obtained from SCC. The minimum price per standard is $15.00; all orders for standards of more than fifteen pages will be charged $1.00 per page. Summaries of these drafts may also be viewed on-line.

The deadline date for comments appears after each draft. Readers are urged to send their comments on these drafts as soon as possible to the address below. Comments, enquiries or orders for any of the draft standards appearing in this or subsequent Europe '92 issues should be directed to:

Information Division
Standards Council of Canada
350 Sparks Street
Ottawa, Ontario K1P 6N7
Ottawa area: (613)238-3222, ext. 126
Toll-free: 1-800-267-8220, ext. 126
Fax: (613)995-4564

prAMD 1 to EN 140
Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 3

prHD 367 S2
On-load tap changers
Date of issue: 1990-12-01
Comment deadline date: 1991-05-15
Number of pages: 5

prEN 415-1
Packaging machine safety - Part 1: Common requirements
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 30

prEN 422
Technical safety requirements for the design and construction of blow moulding machines intended for the production of hollow articles made from plastics
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 25

prEN 423
Resilient floorcoverings - Determination of the effect of stains
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 6

prEN 424
Resilient floorcoverings - Determination of the effect of the simulated movement of a furniture leg
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 5

prEN 425
Resilient floorcoverings - Determination of the effect of a castor chair
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 5

prEN 426
Resilient floorcoverings - Determination of width, length, flatness and straightness
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 427
Resilient floorcoverings - Determination of the side length and squareness of tiles
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 428
Resilient floorcoverings - Determination of overall thickness
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 429
Resilient floorcoverings - Determination of the thickness of layers
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 430
Resilient floorcoverings - Determination of mass per unit area
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 431
Resilient floorcoverings - Determination of peel resistance
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 432
Resilient floorcoverings - Determination of shear strength
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 433
Resilient floorcoverings - Determination of static indentation
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 434
Resilient floorcoverings - Determination of dimensional stability and curling after exposure to heat
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 5

prEN 435
Resilient floorcoverings - Determination of flexibility
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 4

prEN 436
Resilient floorcoverings - Determination of mass per unit volume
Date of issue: 1990-12-01
Comment deadline date: 1991-06-05
Number of pages: 7

prEN 437
Appliances using combustible gases - Test gases, test pressures and categories of appliances
Date of issue: 1990-12-01
Comment deadline date: 1991-06-19
Number of pages: 34

prEN 443
Protective helmets for firefighters
Date of issue: 1990-12-01
Comment deadline date: 1991-06-19
Number of pages: 29

prEN 444
Non-destructive testing - General principles for radiographic examination of metallic materials by X- and X-rays
Date of issue: 1990-12-01
Comment deadline date: 1991-06-19
Number of pages: 14

prEN 445
Grout for prestressing tendons - Test methods
Date of issue: 1990-12-01
Comment deadline date: 1991-06-21
Number of pages: 11

prEN 446
Grout for prestressing tendons - Grouting procedures
Date of issue: 1990-12-01
Comment deadline date: 1991-06-21
Number of pages: 7

prEN 447
Grout for prestressing tendons - Specifications for common grout
Date of issue: 1990-12-01
Comment deadline date: 1991-06-21
Number of pages: 5

prEN 448
Preinsulated bonded pipe systems for underground hot water networks - Fitting assemblies of steel service pipes, polyurethane thermal insulation and outer casing of high density polyethylene
Date of issue: 1990-12-01
Comment deadline date: 1991-06-21
Number of pages: 30

prEN 452
Swap bodies of class A - Dimensions and general requirements
Date of issue: 1991-01-01
Comment deadline date: 1991-07-23
Number of pages: 18

prEN 453
Food processing machinery - Dough mixers - Safety and hygiene requirements
Date of issue: 1991-01-01
Comment deadline date: 1991-07-23
Number of pages: 11

prEN 454
Food processing machinery - Planetary mixers - Safety and hygiene requirements
Date of issue: 1991-01-01
Comment deadline date: 1991-07-23
Number of pages: 13

prEN 10 002-4
Metallic materials - Part 1: Verification of extensometers used in uniaxial testing
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 8

prEN 10 109-1
Metallic materials - Hardness test - Part 1: Rockwell superficial test (scales 15N, 30N, 45N, 15T, 30T, and 45T)
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 9

prEN 10 109-2
Metallic materials - Hardness test - Part 2: Verification of Rockwell superficial hardness testing machines (scales 15N, 30N, 45N, 15T, 30T, and 45T)
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 8

prEN 10 109-3
Metallic materials - Hardness test - Part 3: Calibration of standardized blocks to be used for Rockwell superficial hardness testing machines (scales 15N, 30N, 45N, 15T, 30T, and 45T)
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 6

prEN 10 155
Structural steels with improved atmospheric corrosion resistance - Technical delivery conditions
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 31

prEN 10 164
Steel products with improved deformation properties perpendicular to the surface of the product - Technical delivery conditions
Date of issue: 1991-01-01
Comment deadline date: 1991-07-09
Number of pages: 13

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